

1. An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon configured to be inserted into the cavity,

a lumen connected to the balloon for inflating the balloon when positioned within the cavity, and

the balloon being formed of a flexible, expandable material which includes a sufficient quantity of an x-ray-absorbing material that when inflated and inside the cavity, the balloon's peripheral edges, essentially tangential to a line of sight in an x-ray image, can be seen in such an x-ray image taken from outside the cavity.

2. The applicator device of claim 1, wherein the x-ray absorption density of the balloon wall is such as to absorb about 5% of radiation during treatment, at a selected energy level of the radiation.

3. The applicator device of claim 1, wherein the x-ray absorbing material is integrated into the flexible, expandable material of the balloon and comprises about 3% to 5% by weight barium sulfate.

4. The applicator device of claim 1, wherein the x-ray absorbent material of the balloon is sufficiently low in concentration as to absorb no more than about 5% of x-ray radiation having an energy of about 15-40 kV at the balloon surface, when the x-ray penetrate the balloon approximately normal to the balloon surface.

5. The applicator device of claim 1, wherein the x-ray absorbing material in the balloon is of such concentration that, in an x-ray view of the balloon, the portion of the x-ray view at essentially a tangent of the balloon is a factor of about 15 to 25 times more absorbent, due to an effective path length about 15 to 25 times greater, than a portion normal to the balloon wall.

6. The applicator device of claim 1, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the balloon.

7. A method for determining the position of a balloon applicator placed in a cavity within human tissue, comprising:

providing an applicator device including an inflatable
balloon configured to be inserted into the cavity, a lumen
connected to the balloon for inflating the balloon when
positioned within the cavity, and the balloon being formed of a
5 flexible, expandable material which includes a sufficient
quantity of an x-ray absorbing material that when inflated and
inside the cavity, the balloon's peripheral edges, essentially
tangential to a line of site in an x-ray image, can be seen in
such an x-ray image taken from outside the cavity,

10 inserting the applicator with the balloon into the cavity,
and inflating the balloon using the lumen, and

forming an x-ray image of the inflated balloon in the cavity
and detecting the position of the balloon relative to the
surrounding tissues by observation of the walls of the balloon
15 which appear in the x-ray image essentially along the tangent to
the balloon wall, where x-ray absorption is maximum.

8. The method of claim 7, wherein the x-ray absorbing
material in the balloon is of such concentration that, in an x-
20 ray view of the balloon, the portion of the x-ray view at
essentially a tangent of the balloon is a factor of about 15 to
25 times more absorbent than a portion normal to the balloon
wall.

9. The method of claim 7, wherein the x-ray absorbing material comprises about 3% to 5% by weight barium sulfate in the balloon wall material.

5 10. The method of claim 7, wherein the balloon has a wall thickness which varies at different portions of the balloon, causing higher x-ray absorption in some areas than others, to control dose distribution to different areas of the tissue to be treated when x-ray radiation is delivered from within the
10 balloon.

11. An applicator for radiation treatment of a cavity within human tissue, comprising:

15 an inflatable balloon insertable into the cavity in a deflated state,

 a lumen connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation inserted into the lumen,

20 the balloon being configured to reach a desired general shape when inflated, and

 the balloon having a wall thickness which varies in different parts of the balloon so as to control the inflated shape of the balloon, thicker areas tending not to expand as

extensively as thinner areas of the balloon wall.

12. The applicator of claim 11, wherein some portions of the balloon wall have a thickness which is a factor of about two
5 times thicker than other areas of the balloon wall.

13. The applicator of claim 11, wherein the variation in balloon wall thickness is such as to restrict the expansion of thicker regions of the balloon, when the balloon is inflated, to
10 about 70% compared to the same balloon geometry without the wall thickness variations.

14. The applicator of claim 11, wherein the balloon wall thickness variation is configured so as to produce the general
15 shape of a football, a hotdog, a pear or a truncated cone.

15. An applicator for radiation treatment of a cavity within human tissue, comprising;

an inflatable balloon insertable into the cavity in a
20 deflated state,

a flexible shaft connected to the balloon for inflation of the balloon following insertion into the cavity and for receiving a source of radiation,

the balloon being configured to reach a desired general shape when inflated, so as to engage a wall of the balloon against tissue surrounding the cavity, and

5 wherein the balloon wall has one or more ribs configured to restrict expansion along the lines of the ribs and thus to control the shape of the balloon upon inflation, to the desired general shape.

10 16. The applicator of claim 15, wherein the flexible shaft is arranged longitudinally relative to the balloon, and wherein at least one said rib extends circumferentially on the balloon, generally in a plane transverse to the flexible shaft.

15 17. The applicator of claim 15, wherein the rib or ribs are formed on the inside of the balloon wall.

18. The applicator of claim 15, wherein the rib or ribs are formed on the outside of the balloon wall.

20 19. The applicator of claim 15, further including a surgical drain comprising a plurality of said ribs arranged on the outside surface of the balloon so as to form channels along which seroma and other fluids from the cavity can flow in a

direction toward an opening of the cavity into which the applicator has been inserted.

20. The applicator of claim 19, wherein the flexible shaft
5 includes drain holes for withdrawing liquids from the cavity via at least one duct in the shaft and wherein the ribs are arranged to form said channels in a way to conduct liquids toward the drain holes.

10 21. The applicator of claim 20, wherein the flexible shaft includes at least one additional drain opening at a distal end of the flexible shaft for collecting fluids from the cavity.

15 22. An applicator for use in administering radiation to a cavity in living tissue, comprising:

at least two inflatable balloons positioned side by side and connected so as to be insertable into the tissue cavity together when collapsed, and a flexible shaft connected to the balloons with an inflation lumen for the balloons, at least one of the
20 balloons having a guide within the balloon connected to a channel in the shaft for receiving a radiation source at a peripheral position in the balloon to deliver radiation to walls of the cavity.

23. The applicator of claim 22, wherein each balloon has a guide within the balloon for receiving a radiation source.

24. The applicator of claim 22, wherein the balloons are
5 bonded together.

25. The applicator of claim 22, wherein at least three balloons are included in the applicator, secured to the flexible shaft which is located generally centrally in the applicator, and
10 each balloon carrying a guide for receiving a source of radiation.

26. The applicator of claim 25, wherein the plurality of balloons are radially disposed around the flexible shaft and are
15 of different sizes when inflated, whereby radiation sources can be located along the walls of an irregularly shaped cavity.

27. The applicator of claim 26, with the balloons in the cavity and inflated and with an isotope radiation source in the
20 guide, irradiating the cavity.

28. The applicator of claim 26, the applicator including at least four balloons radially disposed around the flexible shaft,

and the applicator inserted into a tissue cavity and the balloons inflated, the cavity being irregular in shape and the balloons together assuming generally the shape of the cavity and extending into irregularities.

5

29 . The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with an isotope radiation source in the guide.

10

30. The applicator of claim 22, inserted into the tissue cavity and the balloons inflated, in combination with a miniature switchable x-ray tube radiation source in the guide.

15

31. An applicator for use in administering radiation to a cavity in living tissue, comprising;

outer and inner inflatable balloons, the inner balloon being positioned within the outer balloon and the balloons being connected and insertable into the tissue cavity when collapsed,

20

a shaft connected to the balloons with an inflation lumen for the balloons, and the shaft extending into the inner balloon and including a channel for receiving a radiation source to deliver radiation to walls of the cavity,

the outer wall of the inner balloon being substantially in

contact with the inner wall of the outer balloon and bonded there to except at a particular desired area of the balloon where the two balloons are unbonded, and

the unbonded area between the two balloons being filled with
5 a contrast medium to limit radiation passing through said area so as to shield cavity tissue immediately adjacent to said area.

32. An applicator for use in administering radiation to a cavity in living tissue, comprising:

10 an inner balloon and an outer balloon, and a flexible shaft with inflation lumens connected to the inner and outer balloons for inflation of each balloon, and

the inner balloon having a plurality of guides secured to the balloon, each guide for receiving a radiation source at a
15 peripheral position relative to the inner balloon, to deliver radiation to walls of the cavity,

whereby expansion of both the outer balloon and the inner balloon is controllable, and whereby the positions of the guides and thus of radiation sources inserted into the guides is
20 controllable so that radiation dose profile to the cavity can be manipulated as needed.

33. The applicator of claim 32, inserted into the tissue

cavity and the balloons inflated, and further including an isotope radiation source in at least one of the guides.

34. The applicator of claim 32, inserted into the tissue
5 cavity and the balloons inflated, and further including miniature switchable x-ray tube sources in at least some of the guides.

35. An applicator for administering radiation therapy to a surgical cavity in living tissue, comprising:

10 an expandable balloon for positioning within the cavity,
a flexible shaft including a lumen connected to the balloon for delivering a fluid to inflate the balloon,

the shaft being highly flexible and pliable at least in an outer or proximal portion of the shaft, positioned to be at the
15 exterior of the cavity, so as to be foldable down adjacent to the skin of a patient during periods when radiation therapy is not being administered, and

a radially extending seal secured to the exterior of the flexible shaft, the seal being soft and pliable and being
20 generally thin and flat and having a size and area much larger than the diameter of the flexible shaft to permit adhering of the seal to the patient's skin surrounding a surgical opening leading to said cavity against leakage of seroma and other liquids from

the wound.

36. The applicator of claim 35, wherein the seal comprises a circular disc of silicone.

5

37. The applicator of claim 35, wherein the seal has a central hole that fits closely over the flexible shaft, essentially sealing against the exterior of the flexible shaft but being slidable along the flexible shaft such that the seal can be moved longitudinally on the lumen for adjustment while still maintaining an essentially sealed relationship with the flexible shaft.

10

38. The applicator of claim 35, wherein the seal comprises a round disc having a generally radial slit extending to a central hole through which the flexible shaft passes, such that the seal can be installed onto the flexible shaft and can be interchanged.

15

39. The applicator of claim 35, wherein the flexible shaft includes a drain channel and at least one hole from the drain channel to the exterior of the flexible shaft, the holes being positioned to be inside the patient's tissue for withdrawal of

20

liquids from the cavity as retained therein by the seal.

40. The applicator of claim 39, with the flexible shaft folded down at the exterior of the cavity, adjacent to the skin of the patient, the drain channel being effective to drain liquids from the cavity while the tube device is folded down.

41. An applicator for facilitating radiation treatment of a cavity inside living tissue, comprising:

10 an inflatable balloon having a collapsed state and an inflated state,

a flexible shaft secured to the balloon and being elongated so as to extend from inside the surgical cavity to outside the surgical cavity when installed, said flexible shaft having a lumen for introducing a fluid to the balloon to inflate the balloon,

20 surface relief means on the exterior of the balloon for providing channels when the balloon is inflated, to allow the flow of liquids from the surgical cavity toward the exit of the surgical cavity, and

at least one drain channel provided in the flexible shaft, positioned to receive draining liquids from the surgical cavity, and means in the flexible shaft for conducting said liquids out

of the surgical cavity through the drain channel.

42. The applicator of claim 41, wherein the flexible shaft has a central longitudinal channel and a series of outer
5 longitudinal channels arranged generally in an annular array around the central longitudinal channel, at least one of the outer channels comprising said drain channel and being open at a distal end of the flexible shaft to collect liquid.

10 43. The applicator of claim 42, wherein the flexible shaft has entry holes proximal of the balloon, communicating with at least one drain channel, providing another location to collect drain liquids.

15 44. The applicator of claim 41, wherein a proximal end of the flexible shaft is branched, one branch having said drain channel and adapted to an aspirator to draw off liquids, another branch having said lumen for inflation of the balloon, and a further branch having a channel for insertion of a radiation
20 delivering source, through said central longitudinal channel.

45. The applicator of claim 44, wherein said lumen comprises one of the outer channels.

46. The applicator of claim 44, wherein the balloon includes guides to receive the radiation delivery source, said guides connected to said central longitudinal channel and said further branch.

5

47. The applicator of claim 41, wherein the surface relief means comprises longitudinally extending ridges on the exterior of the balloon, providing channels between adjacent ridges.

10

48. The applicator of claim 47, wherein the ridges are interrupted in their length, providing for cross flow of liquids between channels.

15

49. The applicator of claim 41, wherein the surface relief means comprises bumps extending outwardly on the exterior of the balloon.

20

50. The applicator of claim 41, wherein the surface relief means comprises grooves extending inwardly on the exterior surface of the balloon.

51. An applicator device for facilitating radiation treatment of a cavity within human tissue, comprising:

an inflatable balloon configured to be inserted into the cavity when uninflated,

a flexible shaft connected to the balloon for inflating the balloon when positioned within the cavity, and

5 the flexible shaft having a stiffener on a portion of the shaft within the balloon, the stiffener comprising a sleeve tightly engaging over the other surface of the flexible shaft.

10 52. The applicator of claim 51, wherein the stiffener comprises a heat shrink material over the shaft within the balloon.